DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
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Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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August 11, 2003

WARNING LETTER
CIN-03-18454

VIA FEDERAL EXPRESS

Mr. Ewart Walter Johnson, Jr.
President
ElectraMold Inc.
3600 Chamberlain Road, Suite 356
Louisville, KY 40241-1714

Dear Mr. Johnson:

An inspection of your medical device manufacturing firm located in Louisville, KY conducted by our investigator on June 17 and 18, 2003, revealed that your firm manufactures lead wires (electrode cables). These products are medical devices as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deviations from the QSR include, but are not limited to, the following:

Management Controls

1. Failure to establish adequate management control to ensure that an effective quality system has been established and maintained. [21 CFR 820.20] For example:

   - Management with executive responsibility has not ensured that the quality policy is understood at all levels of the organization. [21 CFR 820.20(a)] Specifically, the Receiving and Shipping Clerk stated he did not know if the firm had a written quality policy.

- A management representative has not been appointed. [21 CFR 820.20(b)(3)]
- Management with executive responsibility has not conducted reviews of the quality system. [21 CFR 820.20(c)]
- Quality system procedures have not been established. [21 CFR 820.20(e)] For example, there are no procedures for conducting management reviews, for conducting quality audits and for controlling the design process.

2. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR 820.22]

3. Failure to adequately train personnel to perform their assigned responsibilities. [21 CFR 820.25(b)] Specifically, no quality or manufacturing employees have been trained on the quality system regulations.

Production and Process Controls

4. Failure to document the evaluation and investigation of nonconforming product. [21 CFR 820.90(a)] Specifically, there is no documentation of the evaluation and investigation for the spool of incoming grey wire, spools of incoming "black rubber" and 3 boxes of in-process and finished product cords the FDA investigator found in the "Quarantine and "Rejected Area". These products also did not contain "Rejection" tags as required by "NONCONFORMING MATERIAL CONTROL" procedure.

5. Failure to document rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, in the device history record. [21 CFR 820.90(b)(2)]

6. Failure to document the disposition of nonconforming product. [21 CFR 820.90(b) (1)]. Specifically, two of the eleven device history records reviewed (lots 21903 and 220581) had fewer lead wires placed in inventory then assembled. The disposition of the lead wires not placed in inventory is not documented.

7. Failure to document the acceptance or rejection activities for incoming components. [21 CFR 820.80(b)] Specifically, there is no documentation for the acceptance of all electric cord component product lots (such as the "Quality Assurance Continuity Test" forms).

8. Failure to document the finished device acceptance activities performed on the lead wires. [21 CFR 820.80(e)] Specifically, the "Quality Assurance Continuity Test" form was not completed for 11 of the 11 device history records reviewed.

9. Failure to define the specified requirements for all receiving and finished devices testing. [21 CFR 820.80(b) and (d)] Specifically the "Assembly Inspection and Functional Testing" procedure does not define the continuity test specifications nor does the "Final Inspection and Test" procedure define what "final inspection and test" must be performed. This procedure also does not specify the sample size for these tests.

10. Failure to include a copy of the primary identification label and labeling used for each production unit in the device history record. [21 CFR 820.184(e)]

11. Failure to validate and approve according to established procedures production processes whose results can not be fully verified by subsequent inspection and test. [21 CFR 820.75(a)] For example, the injection molding of the cable assemblies utilizing the [redacted]" has not been validated.

12. Failure to evaluate, define, and maintain a list of acceptable suppliers, and failure to establish procedures to ensure that all purchased or otherwise received products and services conform to specified requirements. [21 CFR 820.50]

Corrective and Preventive Actions

13. Failure to establish procedures for implementing corrective and preventive actions, including failure to document corrective and preventive activities, including analysis of quality data sources, investigations of causes of nonconformances, and implementation of corrective and preventive actions. [21 CFR 820.100]

14. Failure to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report (MDR). [21 CFR 820.198(a)(3)] Specifically, the complaint procedure does not address reviewing complaints to determine if the are MDR reportable.

15. Failure to develop written Medical Device Reporting procedures. [21 CFR 803.17]

Design Controls

16. Failure to perform design control activities and establish Design History Files for the lead wires .[21 CFR 820.30(j)]

17. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. [21 CFR 820.30]

18. Failure to list the lead wires with FDA. [21 CFR 807.20(a)]

In addition to meeting the requirements listed in 21 CFR 803, 806, 807 and 820, the electrode cables (lead wires) manufactured by your firm are also required to meet the regulations in 21 CFR 898, Performance Standards for Electrode Lead Wires and Patient Cables. Thus any connector in a cable or lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with sub clause 56.3(c) of the International Electrotechnical Commission (IEC) 601-1: Medical Electrical Equipment. You are required to determine compliance with this standard by inspection and by applying the test requirements and test methods of subclasses 56.3(c) of IEC 601-1. This testing must be documented.

You should know that deficiencies listed above are serious violations of the law. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president of ElectraMold Inc., it is your responsibility to assure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations listed above.. In addition, please submit any additional documentation to show the corrections initiated in conformance with the requirements of the Quality System Regulation. If corrective action cannot be completed within fifteen (15) working days, state the reason for

the delay and the timeframe within which the corrections will be completed.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Your written response to this Warning Letter should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, extension 167, or you may forward a facsimile to her at (513) 679-2773.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District